IMPACt-LBP

Implementation of the American College of Physicians Guideline for Low Back Pain: A cluster randomized trial

UG3 / U24 Demonstration Project

NIH Collaboratory Steering Committee
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- National Center For Complementary & Integrative Health (NCCIH, Primary)
- Eunice Kennedy Shriver National Institute Of Child Health & Human Development (NICHD, Secondary)
- National Institute Of Arthritis And Musculoskeletal And Skin Diseases (NIAMS, Secondary)

Overarching Project Goal

To implement the American College of Physicians Low Back Pain Guideline by evaluating the impact of the Primary Spine Practitioner (PSP) model in 3 academic Health Care Systems (HCS) and then evaluating its effectiveness by comparing it to usual medical care alone in patients age 18 and older suffering from LBP.

PSP Model

- Multi-disciplinary collaborative care that includes doctors of chiropractic (DC) and physical therapists (PT) as first line providers for LBP.
- Treatment approaches includes non-pharmacological approaches recommended by the ACP LBP guideline, including spinal manipulation and exercise.

Specific Aims

UG3 Planning Phase

1. Finalize the infrastructure required to implement the Primary Spine Practitioner (PSP) model for LBP in 3 academic HCS
2. Refine and prepare to implement a study protocol developed to test the effectiveness of the PSP model using a pragmatic, rigorous, multi-site, cluster-randomized controlled trial.

Specific Aims

UH3 Demonstration Phase

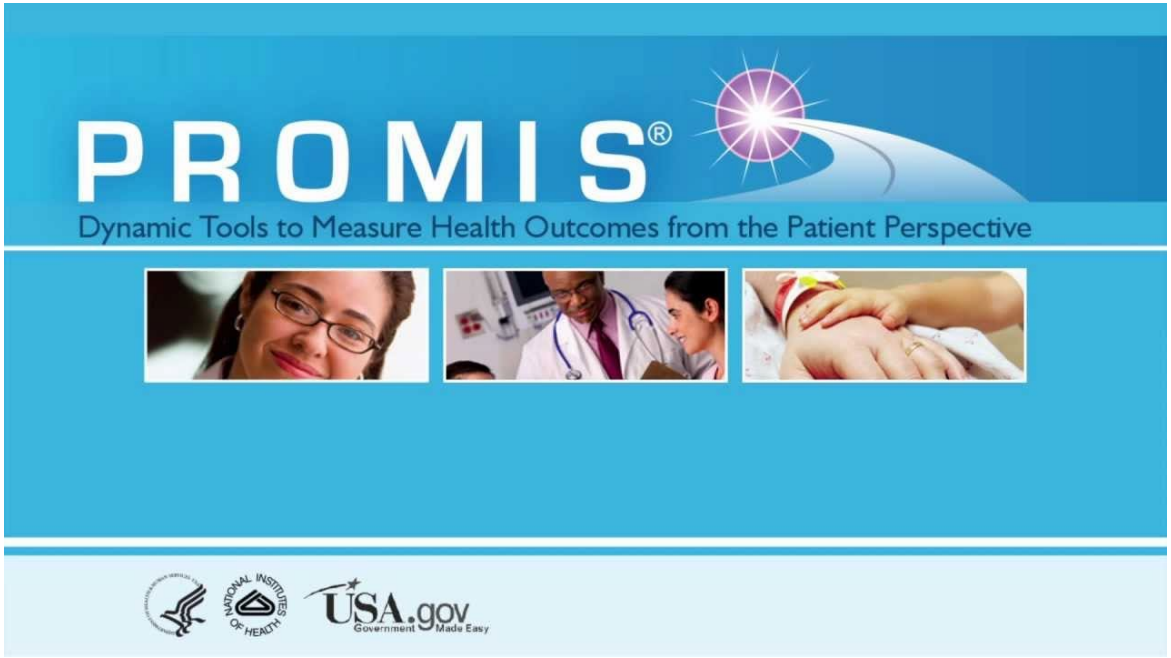
1. Integrate new organizational policies and procedures required to facilitate implementation of the PSP model for patients with LBP at 3 academic HCS.
2. Determine the comparative effectiveness of the PSP model vs usual care alone for patients with LBP. Estimate and compare medical resource use and costs of implementing the PSP model vs usual care alone for patients suffering from LBP.
3. Evaluate patient, provider, system and policy level barriers and facilitators to implementing the PSP model using a mixed method, process evaluation approach.

Study Design

- Pragmatic multi-site two-arm cluster-randomized trial with the unit of randomization at the primary care clinic level.
- ~22 Family Medicine, Primary Care and General Internal Medicine Clinics will be included.
- A total of ~1,800 patients >18 years with a primary complaint of LBP who contact a participating primary care clinic to make an appointment with a primary care provider.

Co-Primary Endpoints

- Change in PROMIS Physical Function from baseline to 3 months
- Change in PROMIS Pain Interference from baseline to 3 months.



Lessons Learned from Year 1

- **Recruitment**
  - Original plan was abstracting data from the EHR under a waiver of consent.
  - We learned that sites would need dedicated research staff at the scheduling hub to ensure adequate recruitment.
- **Consent**
  - Original plan was waiver of consent.
  - Proceeding with waiver of documentation of consent.
- **Data Collection**
  - Original plan was EHR-only abstraction.
  - Data collection from HCS sites will be EHR + REDCap + texting.
- **PSP clinics**
  - Original plan was to engage PSP clinics as research sites.
  - We learned that data collection from PSP sites is not feasible.
- **Identification and commitment from clinics**
  - Clinics were identified in year 1 based on select criteria, however, securing agreements from clinics in year 1 was agreed to be too far away from the time of study initiation.

Ongoing Transition Issues

Regulatory approvals

- Protocol-level submission to the sIRB has been done.
- We anticipate site-level submission to the sIRB this year.
- Site level approvals may not all happen in year 1.
- Additionally, the PRC will not meet until June 24, so feedback won't be received until the end of planning year 1.

Qualitative interviews

- This milestone was moved from year 2 to year 1 at the request of NIH.
- 2 of the 3 sites moved forward with relative ease (determinations from the IRBs were relatively quick for the qualitative work).

Sustainability for UH3

- Using qualitative work to facilitate implementation of the PSP model at intervention clinics.
- Regular outreach/contact with PSP and PCP clinics to sustain engagement.
- Providing access to training and tools via an IMPACt-LBP website.
- Closely monitoring patient compliance with data collection of PROs.

Challenges

- Complex multi-site trial
- Recruitment
- Patient compliance with PSP clinic visits
- Retention

Barriers Scorecard

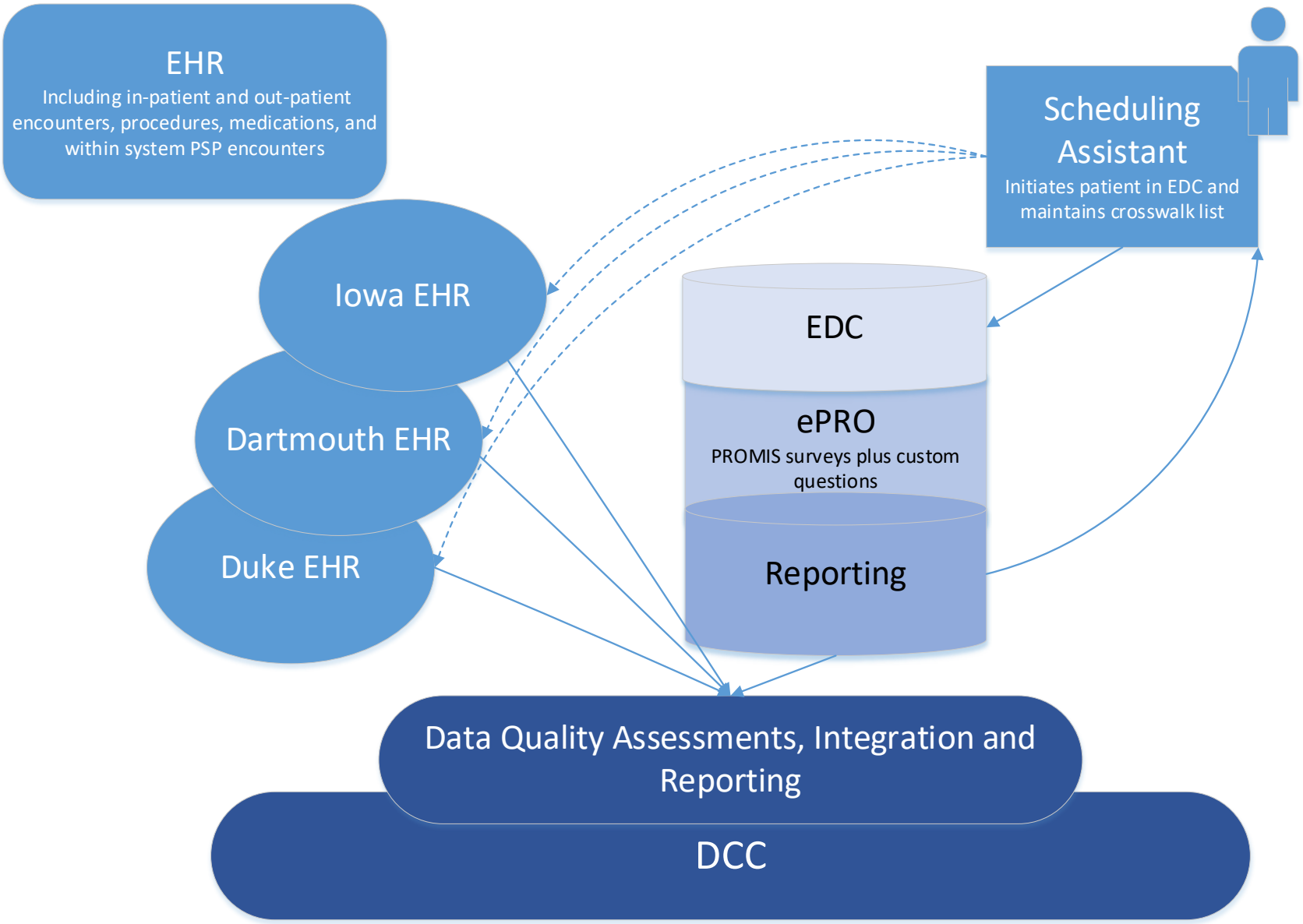
Barrier	Level of Difficulty*				
	1	2	3	4	5
Enrollment and engagement of patients/subjects				x	
Engagement of clinicians and health systems		x			
Data collection and merging datasets			x		
Regulatory issues (IRBs and consent)			x		
Stability of control intervention		x			
Implementing/delivering intervention across healthcare organizations				x	

*Your best guess!
1 = little difficulty
5 = extreme difficulty

Data Collection to Ascertain Outcomes

- Data from multiple sources
  - EHR:
    - Enrolled Cohort: Patient-level LDS of participants, encounters, procedures and medications during the time period of interest, spanning the look-back period through treatment period, as well as any available LBP ePRO questionnaires, with a study-specific id to link to REDCap ePRO - quarterly
    - Longitudinal Cohort: De-identified (no dates) patient-level dataset including data elements of interest above for all patients seen at the participating clinics for LBP during the enrollment period. – at least annually
  - Patient Reported Data (ePRO) Through REDCap:
    - For participants, PROMIS surveys, out-of-system LBP care, opioid usage, ED visits and hospitalizations.

Data Collection



Current Data Sharing Plan

- Limited dataset (Enrolled Cohort):
  - Require Data Use Agreement and IRB approval
  - Custom dataset created to include just the subset of data needed

- De-identified dataset (Longitudinal Cohort):
  - Not subject to HIPAA's minimum necessary standards
  - Not required: Data Use Agreement and IRB approval

- De-identified data or limited datasets for proposed use, with appropriate documentation, will be provided via secure transfer methods to the requestor following institutional approval and data use agreements as appropriate.

- In collaboration with the NCCIH, we will develop a process to facilitate access to study data in the format that is most helpful to them.

- We will follow the Department Health and Human Services guidance regarding HIPAA-compliant data sharing

Current Data Sharing Plan

Obstacles:

- Create limited datasets after the trial ends
- Funding to maintain data sharing after the trial ends

Current Data Sharing Plan

→ How will you put the policy from the data sharing work group into practice in your study?

- **Expectations for Collaboratory Trials**: At a minimum, Collaboratory investigators must prepare and share a final research data set upon which the accepted primary pragmatic trial publication is based.
  - We will create a dataset that includes all the information used in the primary pragmatic trial publication.
  - Other datasets will be created based on user request.
  - We will follow the Department Health and Human Services guidance regarding HIPAA-compliant data sharing.
  - We will use a trial data sharing agreement with the user.

Current Data Sharing Plan

The trial data sharing agreement will contain the following stipulations.

- The data will be used for research purposes and not to identify individual subjects.
- The data must be secured using appropriate computer technology with user access controlled.
- The authors of any manuscript resulting from this data must acknowledge the source of the data upon which their manuscript is based.
- Any analyses for the purpose of presentations, abstracts, and/or publications must be coordinated through the IMPACT-LBP Data Dissemination Committee, so that there can be some coordination of analyses to ensure that redundant analyses are not being performed independently.
- All coauthors must be given a chance for review and approval of a draft manuscript prior to submission for publication.

Current Data Sharing Plan

→ What data are you planning to share from your project (individual-level data, group-level data, specific variables/outcomes, etc.)?

- We are planning to share individual and group-level de-identified and limited datasets
- Variables will be selected based on the user request

→ What information did the IRB require about how the data would be shared beyond the study in order to waive informed consent?

→ We did not seek a waiver of consent but rather a waiver of documentation of consent.

Questions?

APPENDIX

Randomization and Eligibility

Clinic and Patient Eligibility

Clinic Eligibility

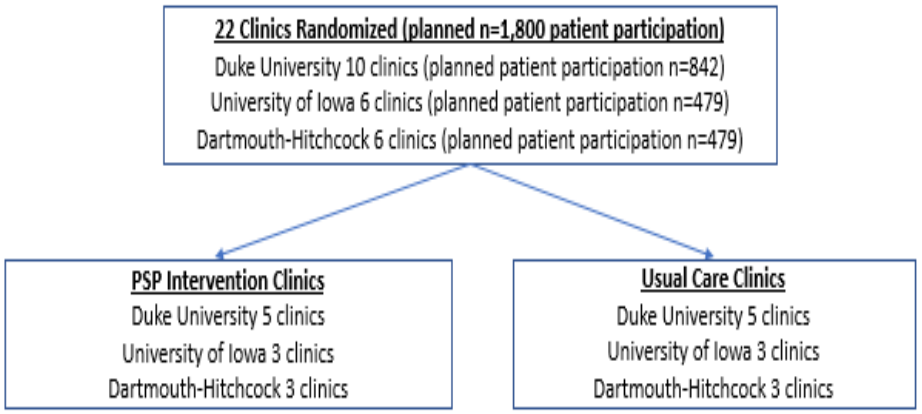
- Affiliated with one of the 3 participating academic HCS;
- Designated as primary care, family medicine or general internal medicine clinics;
- Willing to participate in the PSP model;
- Provide a signed site participation agreement; and
- Had at least n=250 unique patient visits with LBP assessed in UG3 planning year.

Patient Eligibility

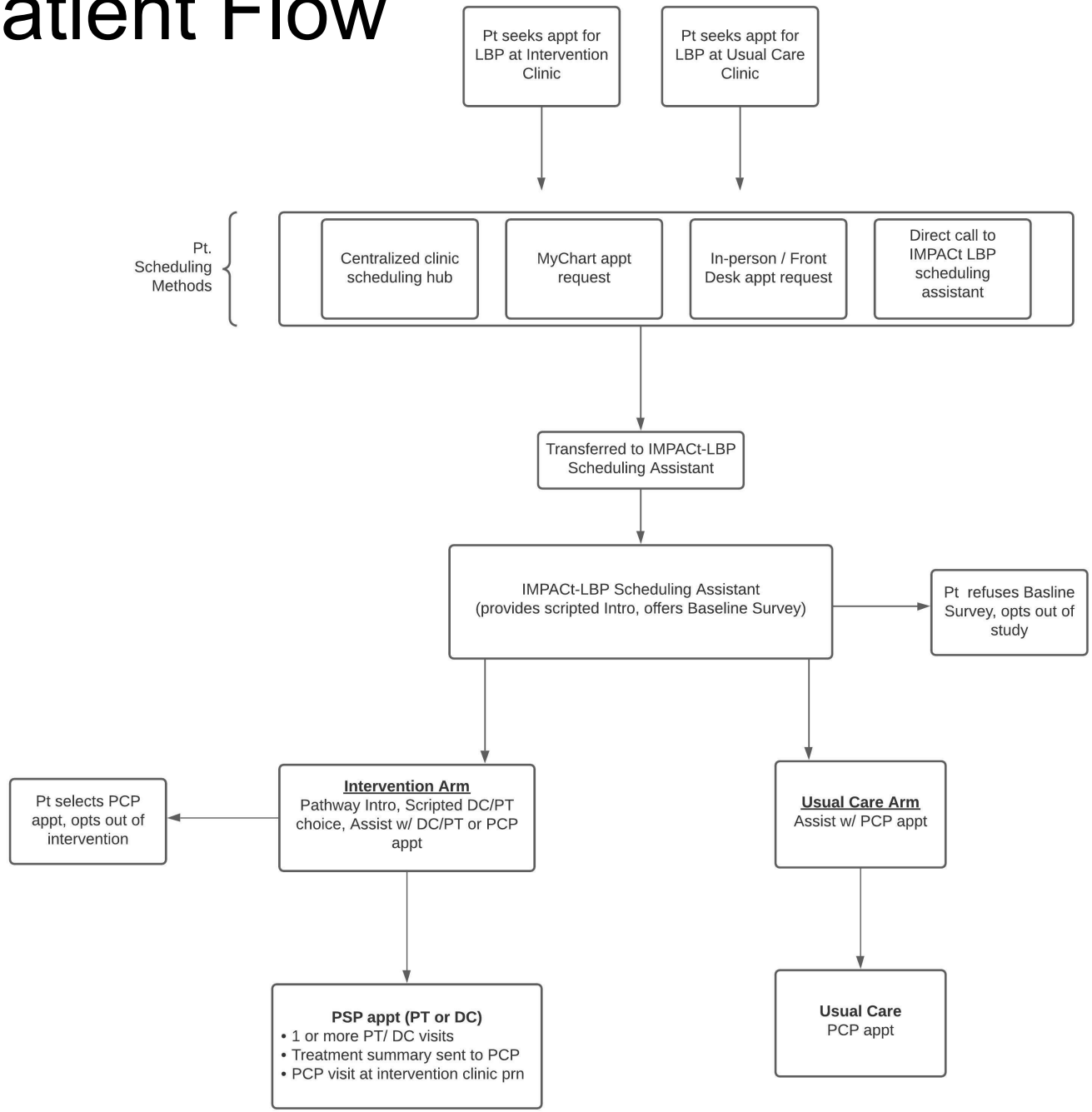
- Adult patients >18 years old;
- Seeking care for LBP at one of the participating clinics; and
- Agree to complete study questionnaires about back pain, quality of life

Primary care clinics allocated 1:1 to each arm

Figure 1. Clinic Randomization



Patient Flow



Secondary Endpoints

- Evaluated at all follow-up time points (3, 6, 12, 24* Months)
  - LBP-related
    - Imaging and Diagnostic Testing
    - Injection Procedures
    - Surgical Procedures
    - Medication Prescriptions
    - Provider visits
  - Hospital Admissions
  - Emergency Room Visits

*24 month data collection will only be done on patients who enroll in the first 18 months of recruitment

Secondary Endpoints – Other Schedules

Description	Baseline	3 Months	6 Months	12 Months	24 Months*
Pain Catastrophizing	X	X	X	X	X
PROMIS Global-10	X	X	X	X	X
Total Prescribed Opioid Dose	X	X	X	X	X
NIH LBP Questions	X			X	
Patient Satisfaction		X			
Perceived Improvement		X			
Patient Experience		X			

*24 month data collection will only be done on patients who enroll in the first 18 months of recruitment